



PATENT
Docket No.: 20609/261 (PD 02027)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicants : | Jennings et al. |) | Examiner: |
| Serial No. : | 10/686,309 |) | To Be Assigned |
| Cnfrm. No. : | To Be Assigned |) | Art Unit: |
| Filed : | October 15, 2003 |) | To Be Assigned |
| For : | METHODS FOR ASSESSMENT OF PLATELET AGGREGATION |) | |

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98

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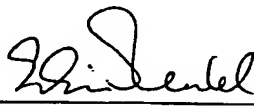
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§ 1.97-1.98, applicants hereby bring to the attention of the
United States Patent and Trademark Office, the enclosed references listed on the attached
PTO-1449 form.

Respectfully submitted,

Date: March 11, 2004


Edwin V. Merkel
Registration No. 40,087

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Clinton Square, P.O. Box 31051
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| Date <u>3/11/04</u> | <u>Wendy L. Barry</u> Wendy L. Barry |

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| Substitute for form 1449A/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/686,309 |
| | | Filing Date | October 15, 2003 |
| | | First Named Inventor | Jennings et al. |
| | | Art Unit | To Be Assigned 1743 |
| | | Examiner Name | To Be Assigned Wallenhorst |
| Attorney Docket Number | 20609/261 (PD 02027) | | |

| U.S. PATENT DOCUMENTS | | | | | |
|--------------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials ¹ | Cite No. ¹ | U.S. Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number - Kind Code ² (if known) | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------------|-----------------------|---|--------------------------------|--|---|----------------|
| Examiner Initials ¹ | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁴ |
| | | Country Code ³ Number ⁴ Kind Code ² (if known) | | | | |
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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|---|-----------------------|---|----------------|
| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| mw | 1 | Kandzari et al., "TARGET versus GUSTO-IV: Appropriate Use of Glycoprotein IIb/IIIa Inhibitors in Acute Coronary Syndromes and Percutaneous Coronary Intervention," <i>Curr. Opin. Cardiol.</i> 17:332-339 (2002) | |
| mw | 2 | Gold et al., "Rapid and Sustained Coronary Artery Recanalization with Combined Bolus Injection of Recombinant Tissue-Type Plasminogen Activator and Monoclonal Antiplatelet GPIIb/IIIa Antibody in a Canine Preparation," <i>Circulation</i> 77:670-677 (1988) | |
| mw | 3 | The EPIC Investigators, "Use of a Monoclonal Antibody Directed Against the Platelet Glycoprotein IIb/IIIa Receptor in High-Risk Coronary Angioplasty," <i>N. Engl. Med.</i> 330:956-961 (1994) | |
| mw | 4 | Steinhubl Sr. et al., "Point-of-Care Measured Platelet Inhibition Correlates with a Reduced Risk of an Adverse Cardiac Event After Percutaneous Coronary Intervention," <i>Circulation</i> 103:2572-2578 (2001) | |

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|--------------------|---------------------|-----------------|---------|
| Examiner Signature | maureen Wallenhorst | Date Considered | 9-13-05 |
|--------------------|---------------------|-----------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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| Substitute for form 1449B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Application Number | 10/686,309 |
| | | | | Filing Date | October 15, 2003 |
| | | | | First Named Inventor | Jennings et al. |
| | | | | Group Art Unit | To Be Assigned 1743 |
| | | | | Examiner Name | To Be Assigned Wullenhorst |
| Sheet | 2 | of | 2 | Attorney Docket Number | 20609/261 (PD 02027) |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|---|-----------------------|---|----------------|
| Examiner Initials [*] | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| mw | 5 | Jennings et al., "Expression of Ligan-Induced Binding Sites on Glycoprotein IIb/IIIa Complexes and the Effect of Various Inhibitors," <i>Am. Heart J.</i> 135:S179-S183 (1998) | |
| mw | 6 | Kereiakes et al., "Time Course, Magnitude and Consistency of Platelet Inhibition by Abciximab, Tirofiban, or Eptifibatide in Patients with Unstable Angina Pectoris Undergoing Percutaneous Coronary Intervention," <i>Am. J. Cardiol.</i> 84:391-395 (1999) | |
| mw | 7 | Simon et al., "A Comparative Study of Light Transmission Aggregometry and Automated Bedside Platelet Function Assay in Patients Undergoing Percutaneous Coronary Intervention and Receiving Abciximab, Eptifibatide, or Tirofiban," <i>Cathet. and Cardiovasc. Intervent.</i> 52:425-432 (2001) | |
| mw | 8 | Phillips et al., "Effect of Ca ⁺⁺ on Integrin TM GPIIb-IIIa Interactions: Enhanced GPIIb-IIIa Binding and Inhibition of Platelet Aggregation by Reductions in the Concentration of Ionized Calcium in Plasma Anticoagulated with Citrate," <i>Circulation</i> 96:1488-1494 (1997) | |
| mw | 9 | Nannizzi-Alaimo et al., "Effect of Citrate Anticoagulation and Platelet Agonist Concentration on the Inhibitory Activities of GPIIb-IIIa Antagonists," <i>Circulation</i> 100:1710 (1999) | |
| mw | 10 | Kereiakes et al., "Differential Effects of Citrate Versus PPACK Anticoagulation on Measured Platelet Inhibition by Abciximab, Eptifibatide and Tirofiban," <i>J. Thromb. Thrombolysis</i> 12:123-127 (2001) | |
| mw | 11 | Jennings et al., "The Pharmacodynamics of Parental Glycoprotein IIb/IIIa Inhibitors," <i>J. Interv. Cardiol.</i> 15:45-60 (2002) | |
| mw | 12 | Wheeler et al., "The Ultegra Rapid Platelet-Function Assay: Comparison to Standard Platelet Function Assays in Patients Undergoing Percutaneous Coronary Intervention with Abciximab Therapy," <i>Am. Heart J.</i> 143:602-611 (2002) | |
| mw | 13 | Lakkis et al., "Use of ICHOR-Platelet Works to Assess Platelet Function in Patients Treated with GP IIb/IIIa Inhibitors," <i>Cathet. and Cardiovasc. Intervent.</i> 53:346-351 (2001) | |
| mw | 14 | Nannizzi-Alaimo et al., "GPIIb-IIIa Antagonists Demonstrate a Dose-Dependent Inhibition and Potentiation of Soluble CD40L (CD154) Release During Platelet Stimulation," <i>Circulation</i> 104(suppl II):II-318 (2001) (Abstract #1533) | |
| mw | 15 | Andre et al., "Platelet-Derived CD40L: The Switch-Hitting Player of Cardiovascular Disease," <i>Circulation</i> 106:896-899 (2002) | |

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| Examiner Signature | Maureen Wullenhorst | Date Considered | 9-13-05 |
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| | |) | Art Unit: |
| Cnfrm. No. : | To Be Assigned |) | To Be Assigned |
| | |) | |
| Filed : | October 15, 2003 |) | |
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| For : | METHODS FOR ASSESSMENT OF |) | |
| | PLATELET AGGREGATION |) | |

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98**


Mail Stop:
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P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§ 1.97-1.98, applicants hereby bring to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO-1449 form. The pertinence of these references is indicated in the accompanying search report for the corresponding PCT application. One of the references (Jennings et al.) is not cited herein, because this reference was previously cited in an earlier-submitted information disclosure statement.

Respectfully submitted,

Date: May 12, 2004


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Registration No. 40,087

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| Date 5/13/04 | Wendy L. Barry |

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| | | Examiner Name | To Be Assigned Wallenhurst |
| Sheet | 1 | Attorney Docket Number | 20609/261 (PD 02027) |

| U.S. PATENT DOCUMENTS | | | | | |
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| Examiner Initials ¹ | Cite No. ¹ | U.S. Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number - Kind Code ² (if known) | | | |
| mw | 1 | US-4,090,129 | 05/16/1978 | Gear | |
| mw | 2 | US-6,043,871 | 03/28/2000 | Solen et al. | |
| mw | 3 | US-6,410,337 | 06/25/2002 | Brady et al. | |
| mw | 4 | US-2002/0048575 A1 | 03/25/2002 | Perkes | |
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| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
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| mw | 5 | Aursnes et al., "Shear Stress Activation of Platelets with Subsequent Refractoriness," <i>Thrombosis Research</i> , 45:29-37 (1987). | |
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| Examiner Signature | Margaret Wallenhurst | Date Considered | 9-13-05 |
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